Recommendations of the SEC (Oncology) made in its 11th/26 meeting held on 07.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/05/25 Online Submission (47379) CT-P44 (Daratumumab)	M/s. IQVIA RDS (India) Private Limited	In light of earlier SEC recommendation dated 20.02.2025, the firm presented phase I/III protocol no.: CT-P44 3.1 version vo. 1.0 dated 21-OCT-2024. After detailed deliberation, the committee opined that firm shall submit Safety data, Tolerability data, Co-morbidity, Number of treatment cycle completed, drop out, SAE, AE…etc in higher number of subject participate (approximately 100) in other countries including Vietnam and Brazil along with recommendation of DSMB to CDSCO for further review by the committee.
2.	CT/33/26 Online Submission (55197) BMS-986545 / PUMITAMIG	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase II/III clinical study protocol no.:CA266-0004 amendment 01 dated 27-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1. Increase the number of subjects from India. 2. Day care of center should not be a part of clinical trial.
3.	CT/34/26 Online Submission (55345) BMS-986545 / PUMITAMIG	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase II/III clinical study Protocol No.:CA266-0003 amendment 01 dated 09-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1. More geographically distributed government site shall be included

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			in the study. 2. Increase the number of subjects from India. 3. Day care of center should not be a part of clinical trial.
4.	CT/36/26 Online Submission (55389) PF-08634404, 20 mg/ml, Concentrate for solution for infusion	M/s. Pfizer Limited	The firm presented phase II clinical study protocol no.: C6461014 Final Protocol Amendment 2 dated 19-FEB-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
Biological Division			
5.	BIO/CT04/FF/2025/ 52329 Nivolumab 10 mg/ml concentrate for solution for infusion.	M/s. Shilpa Biologicals Private Limited	In light of earlier recommendation of SEC (Oncology) dated 26.02.2026, the firm presented revised protocol to conduct a Phase I/III clinical trial titled “A Phase I/III, Randomized, Multicentre, Double-Blind, Two-Arm, Parallel-Group, Comparative Clinical Study to Investigate the Efficacy, Immunogenicity, Safety, and Pharmacokinetics of SBPL-Nivolumab Biosimilar Versus Reference Nivolumab in Study Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)” as per Protocol No. 25-AGCR-004, Version 5.0 dated 23.03.2026. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/III clinical trial as per the protocol presented by the firm.
6.	BIO/CT21/FF/2025/ 53712 Denosumab Injection 120 mg/1.7 mL vial	M/s. Enzene Biosciences Ltd.	The firm presented the proposal for the grant of permission for an additional strength and presentation- Denosumab Injection 120 mg/1.7 mL vial- as an extension of the already approved biosimilar Denosumab Injection 60 mg/1 mL Pre-Filled Syringe for following additional indication: • Prevention of skeletal-related events in patients with bone

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			metastases from solid tumors The firm also requested for waiver of local clinical trial, proposing extrapolation of clinical data from the 60 mg product conducted in osteoporosis. After detailed deliberation, the committee noted that no clinical data for the proposed 120 mg strength are available. The committee recommended that the firm shall conduct a bridging clinical study at the proposed 120 mg dose. Further, the Committee opined that the firm's proposal for approval of Denosumab Injection 120 mg/1.7 mL vial, by way of extrapolation of clinical data from the 60 mg product conducted in osteoporosis, may not be considered.
New Drug Division			
7.	ND/MA/26/000004 Aumolertinib tablet 55 mg	M/s. Glenmark Pharmaceuticals Ltd	The firm presented the proposal for grant of permission to manufacture and market the drug Aumolertinib tablets 55 mg along with justification for Phase III Clinical Trial waiver before the committee. The committee noted that drug is approved in China, EU and UK. The firm has presented Phase III CT study data conducted in the country of origin. The committee noted that there is no data on Indian population. After detailed deliberation, the committee did not consider Phase III CT waiver at this stage and opined that firm should submit the followings for further evaluation and consideration by the committee: 1. Subset analysis data of Phase III Clinical trial on Southeast Asian population. 2. Structured Phase IV Clinical Trial protocol.